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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

STAICOVICI, STEFAN

ART UNIT PAPER NUMBER

1732

DATE MAILED: 12/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/724,007

Applicant(s)

KURK ET AL.

Examiner

Stefan Staicovici

Art Unit

1732

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 and 29-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 29-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on November 28, 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 6, 2003 has been entered.

Response to Amendment

2. Applicants' amendment filed October 6, 2003 has been entered. Claims 1-11 and 29-50 are pending in the instant application.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-11 and 29-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "sharp" in claims 1 and 29 is a relative term that renders the claim indefinite. The term "sharp" is not defined by the claim, the specification does not provide a standard for

ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

The term "comparable" in claim 38 is a relative term that renders the claim indefinite. The term "comparable" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Claims 2-11, 30-37 and 39-50 are rejected as dependent claims.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-2, 5-7 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Jansen *et al.* (US Patent No. 5,376,113).

Jansen *et al.* ('113) teach the claimed mandrel for making a heart valve (valve prostheses), said mandrel (7) having a plurality of ridges containing therebetween contoured surfaces (5) for forming polymer leaflets of said heart valve (valve prostheses) and further including a sharp edge separating a top flat surface (8) from said contoured surfaces (5), said sharp edge corresponding to free edges of said heart valve (valve prostheses) (see Figure 1). It is

submitted that the edge of Jansen *et al.* ('113), as shown in Figure 1, is a sharp edge because said heart valve is not formed in a closed position, but rather in an intermediate position (see col. 2, lines 45-48).

Regarding claim 2, Jansen *et al.* ('113) teach a mandrel (7) having three contoured surfaces (5) defined by three ridges and three scallop regions (6).

In regard to claims 5 and 6, Figure 1 of Jansen *et al.* ('113) teach that the angle between the top surface (8) and the contoured surfaces (5) is no larger than 90 degrees.

Specifically regarding claim 7, Jansen *et al.* ('113) teach a flat top surface (8).

Regarding claim 10, Jansen *et al.* ('113) teach that contoured surfaces (5) are on the outside of mandrel (7).

7. Claims 1-2, 5-7, 10 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by NL 1008349.

NL 1008349 teaches the claimed mandrel for making a heart valve (valve prostheses), said mandrel having a plurality of ridges containing therebetween contoured surfaces for forming polymer leaflets of said heart valve (valve prostheses) and further including a sharp edge separating a top surface from said contoured surfaces, said sharp edge corresponding to free edges of said heart valve (valve prostheses) (see Figure 8A). It is submitted that the edge of NL 1008349, as shown in Figure 8A, is a sharp edge

Regarding claim 2, NL 1008349 teaches a mandrel having three contoured surfaces defined by three ridges and three scallop regions.

In regard to claims 5 and 6, Figure 8A of NL 1008349 teaches that the angle between the top surface (8) and the contoured surfaces (5) is no larger than 90 degrees.

Specifically regarding claim 7, NL 1008349 teaches a flat top surface (8).

Regarding claim 10, NL 1008349 teaches that contoured surfaces (5) are on the outside of mandrel.

In regard to claim 30, NL 1008349 teaches a slightly concave surface.

8. Claims 1, 8, 11, 29 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Pierce *et al.* (US Patent No. 4,364,127).

Pierce *et al.* ('127) teach the claimed mandrel for making a heart valve (valve prostheses), said mandrel (32) having a plurality of ridges extending between contoured surfaces which form scallop regions (30) of said heart valve (14) (see Figures 1 and 6). Further, Pierce *et al.* ('127) teach a top surface (40) formed by shims (35) that define a sharp edge separating the contoured surfaces (see Figures 10 and 11). It is submitted that the edge of Pierce *et al.* ('127), as shown in Figure 11, is a sharp edge.

Regarding claim 8, Pierce *et al.* ('127) teach a top surface having both flat and curved portions (see Figures 1 and 9).

Regarding claim 11, Pierce *et al.* ('127) teach contoured surfaces on the inside of mandrel (32) (see Figures 1 and 6).

In regard to claim 29, Pierce *et al.* ('127) teach a closed configuration of the resulting heart valve such that contoured surfaces of adjacent leaflets form a common boundary (see Figure 11).

Specifically regarding claim 31, Pierce *et al.* ('127) teach a convex surface.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claim 3-4, 9 and 32-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jansen *et al.* (US Patent No. 5,376,113) or NL 1008349 in view of Moe *et al.* (US Patent No. 6,174,331 B1) and Stockum (US Patent No. 4,135,867).

Jansen *et al.* ('113) or NL 1008349 teaches the basic claimed mandrel as described above.

Regarding claims 3-4 and 34, Jansen *et al.* ('113) or NL 1008349 do not teach a dip molding mandrel having a curved edge (radius of curvature). Moe *et al.* ('331) teach a heart valve obtained by dip molding, said heart valve having polymer leaflets which exhibit a radius of curvature and an increased thickness at the edge (see col. 3, lines 50-60; col. 6, lines 31-51 and Figure 6A). Further, it should be noted that it is well known that in a dip molding process, as evidenced by Stockum ('867), a radius of curvature on the mandrel provides for improved releasability of the molded article (see Abstract). It should be noted that upon Applicants' request, the teachings of Stockum ('867) were employed to show that it is well known that in a

dip molding process a radius of curvature on the mandrel provides for improved releasability of the molded article

Furthermore, it is submitted that a dip mold used to make such a configuration includes a radius of curvature in order to increase the thickness of the edge, hence it is submitted that the dip mold (mandrel) of Moe *et al.* ('331) includes an edge having a radius of curvature. Furthermore, it is submitted that the actual radius of curvature is a result-effective variable. In re Antonie, 559 F.2d 618, 195 USPQ 6 (CCPA 1977). Therefore, it would have been obvious for one of ordinary skill in the art to have used routine experimentation to determine an optimum radius of curvature in the mandrel of Jansen *et al.* ('113) or NL 1008349 in view of Moe *et al.* ('331) and Stockum ('867), because Moe *et al.* ('331) specifically teach that a thicker leaflet edge provides for an improved heart valve due to an increased strength to compressive loading and also because, Stockum ('867) teaches that a curved edge improved releasability of the molded article.

In regard to claims 9 and 32-33, Jansen *et al.* ('113) do not teach a dip molding mandrel having a protruding portion away from the edge. Moe *et al.* ('331) teach a heart valve obtained by dip molding, said heart valve having polymer leaflets which exhibit an increased thickness at the edge (see col. 3, lines 50-60 and col. 6, lines 31-51). It is submitted that a dip mold used to make such a configuration includes a protruding portion away from the edge in order to increase the thickness of the edge, hence it is submitted that the dip mold (mandrel) of Moe *et al.* ('331) includes a protruding portion away from the edge. Therefore, it would have been obvious for one of ordinary skill in the art to have provided a protruding portion away from the edge as taught by

Moe *et al.* ('331) in the dip mold of Jansen *et al.* ('113) because, Moe *et al.* ('331) specifically teach that a thicker leaflet edge provides for an improved heart valve due to an increased strength to compressive loading. Furthermore, it is submitted that the actual dimension of the protruding portion, and hence of the groove, is a result-effective variable. In re Antonie, 559 F.2d 618, 195 USPQ 6 (CCPA 1977). Therefore, it would have been obvious for one of ordinary skill in the art to have used routine experimentation to determine an groove dimension in the mandrel of Jansen *et al.* ('113) or NL 1008349 in view of Moe *et al.* ('331) because, Moe *et al.* ('331) specifically teach that a thicker leaflet edge provides for an improved heart valve due to an increased strength to compressive loading and also because a curved edge improves releasability of the molded article.

11. Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jansen *et al.* (US Patent No. 5,376,113) or NL 1008349 in view of Henning *et al.* (US Patent No. 4,575,442).

Jansen *et al.* ('113) or NL 1008349 teaches the basic claimed mandrel as described above.

Regarding claim 35, Jansen *et al.* ('113) or NL 1008349 do not teach a coating the mandrel with a polymeric layer. Henning *et al.* ('442) teach providing a synthetic coating (polymeric) on a dip core (see col. 2, lines 15-22 and col. 3, lines 5-10). Therefore, it would have been obvious for one of ordinary skill in the art to have provided a synthetic coating (polymeric) on the dip mold in the mandrel of Jansen *et al.* ('113) or NL 1008349 because, Henning *et al.* ('442) teach that such a coating provides for an improved surface of the resulting molded product and also because all references teach similar materials, processes and end-products.

12. Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pierce *et al.* (US Patent No. 4,364,127) in view of. Moe *et al.* (US Patent No. 6,174,331 B1).

Pierce *et al.* ('127) teach the basic claimed mandrel as described above.

Regarding claim 36, Pierce *et al.* ('127) do not teach a dip molding mandrel having a curved edge (radius of curvature). Moe *et al.* ('331) teach a heart valve obtained by dip molding, said heart valve having polymer leaflets which exhibit a radius of curvature and an increased thickness at the edge (see col. 3, lines 50-60; col. 6, lines 31-51 and Figure 6A).

Further, it should be noted that it is well known that in a dip molding process, as evidenced by Stockum ('867), a radius of curvature on the mandrel provides for improved releasability of the molded article (see Abstract). It should be noted that upon Applicants' request, the teachings of Stockum ('867) were employed to show that it is well known that in a dip molding process a radius of curvature on the mandrel provides for improved releasability of the molded article

Furthermore, it is submitted that a dip mold used to make such a configuration includes a radius of curvature in order to increase the thickness of the edge, hence it is submitted that the dip mold (mandrel) of Moe *et al.* ('331) includes an edge having a radius of curvature. Furthermore, it is submitted that the actual radius of curvature is a result-effective variable. In re Antonie, 559 F.2d 618, 195 USPQ 6 (CCPA 1977). Therefore, it would have been obvious for one of ordinary skill in the art to have used routine experimentation to determine an optimum radius of curvature in the mandrel of Pierce *et al.* ('127) in view of Moe *et al.* ('331) and in further view of Stockum ('867), because Moe *et al.* ('331) specifically teach that a thicker leaflet

edge provides for an improved heart valve due to an increased strength to compressive loading and also because, Stockum ('867) teaches that a curved edge improves releasability of the molded article.

13. Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pierce *et al.* (US Patent No. 4,364,127) in view of Henning *et al.* (US Patent No. 4,575,442).

Pierce *et al.* ('127) teach the basic claimed mandrel as described above.

Regarding claim 37, Pierce *et al.* ('127) do not teach a coating the mandrel with a polymeric layer. Henning *et al.* ('442) teach providing a synthetic coating (polymeric) on a dip core (see col. 2, lines 15-22 and col. 3, lines 5-10). Therefore, it would have been obvious for one of ordinary skill in the art to have provided a synthetic coating (polymeric) on the dip mold in the mandrel of Pierce *et al.* ('127) because, Henning *et al.* ('442) teach that such a coating provides for an improved surface of the resulting molded product and also because all references teach similar materials, processes and end-products.

Allowable Subject Matter

14. Claim 38-50 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.

Response to Arguments

15. Applicants' remarks filed October 6, 2003 have been considered.

Applicants argue that the art of record does not teach or suggest, either alone or in combination, a mandrel having a sharp edge. However, this argument is drawn to a newly presented claim limitation that has been rejected in this Office Action as set forth above.

Applicants argue that the art of record does not explicitly teach a sharp edge, nor it may be inferred, because “all of these references either require trimming the polymer structures prior to removal, or removing the polymer structures from their respective forms in one piece” (see page 10 of the amendment filed October 6, 2003). In response, it is noted that the edge of Jansen *et al.* (‘113), as shown in Figure 1, is a sharp edge because said heart valve is not formed in a closed position, but rather in an intermediate position (see col. 2, lines 45-48). Further, it is noted that under MPEP §2125, the drawings “can anticipate claims if they clearly show the structure which is claimed.” In re Mraz, 455 F.2d 1069, 173 USPQ 25 (CCPA 1972). As such, it is submitted that, NL 1008349 in Figure 8A, Jansen *et al.* (‘113) in Figure 1, and Pierce *et al.* (‘127) in Figure 11 show a mandrel with a “sharp” edge. The similarities that exist between the mold shown in Figure 8 of the instant application and Figure 1 of Jansen *et al.* (‘113) are also to be noted. Furthermore, it is noted that Applicants’ arguments are drawn to functional aspects of said mandrel such as “*trimming* the polymer structures” and “*removing* the polymer structures...in one piece” (emphasis added). It is noted that in a claim drawn to an apparatus, patentability is determined by the structure of the apparatus and not its functional characteristics.


Conclusion

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stefan Staicovici, Ph.D. whose telephone number is (703) 305-0396 (until December 22, 2003) and (571) 272-1208 (after December 23, 2003). The examiner can normally be reached on Monday-Friday 8:00 AM to 5:30 PM and alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Colaianni, can be reached at (703) 305-5493 and (571) 272-1196 (after December 23, 2003).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0661.

Stefan Staicovici, PhD


Primary Examiner *12/18/03*

AU 1732

December 18, 2003